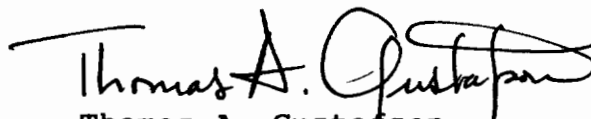


HCFA LEGISLATIVE SUMMARY

JUN 22 1993

THE MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992 (MQSA)

On October 27, 1992, the President signed into law H.R. 6182, the Mammography Quality Standards Act of 1992, Public Law 102-539. This law establishes national quality standards for all facilities providing mammography services in the U.S. As of October 1, 1994, facilities will be required to be certified by the Secretary or a state, if the Secretary has approved the state program.



Thomas A. Gustafson
Acting Director
Office of Legislation and Policy

THE MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992 (MQSA)
Public Law 102-539

Definitions

- o "accreditation body" - a body approved by the Secretary to accredit mammography facilities.
- o "certificate" - a certificate, issued by the Secretary, applicable to the examination or procedure to be conducted, is required before a facility can conduct an examination or procedure involving mammography.
- o mammography "facility" - a hospital, outpatient department, clinic, radiology practice, mobile unit, physician's office or other facility designated by the Secretary that conducts breast cancer screening or diagnosis through mammography. Excludes Veterans Administration facilities.
- o mammography facility "activities" - operation of mammography equipment, processing of the film, viewing conditions for interpretation of the mammogram and initial interpretation.
- o "inspection" - onsite evaluation of the facility by the Secretary or state agency on behalf of the Secretary.
- o "mammogram" - radiographic image produced through mammography.
- o "mammography" - radiography of the breast.
- o "survey" - onsite physics consultation and evaluation performed by a medical physicist.

Certificate Requirement

- o After October 1, 1994, no facility (including any hospital, outpatient department, clinic, radiology practice or mobile unit, or physician's office, but not including a facility of the Department of Veterans Affairs) may conduct an examination or procedure involving screening or diagnostic mammography (including operation of radiologic equipment used to image the breast, interpreting a mammogram, or processing film produced by mammogram equipment) unless the facility obtains a certificate.
- o The facility is responsible for all aspects of quality standards even when processing or interpretation are performed at a different location from where the mammogram is performed.

Issuance/Renewal of Certificates

- o Authorizes the Secretary to issue or renew certificates and provisional certificates to facilities which submit requested information and assurances. A certificate may be issued or renewed for up to 3 years; a provisional certificate may be effective for not longer than 6 months, with a single 90-day extension.

Application for Certificates

- o Requires certificate applications to include a detailed description of the facility's equipment, procedures, and names and qualifications of personnel; proof of accreditation and of an on-site survey by a qualified medical physicist; and assurances that the facility will be operated in accordance with quality standards established by the Secretary, will permit inspections, and will maintain, update, and make available required information. Provides for administrative appeal of a denial of certification.

State Program

- o Permits the Secretary to authorize a state to carry out the certification program and to implement standards established by the Secretary with respect to mammography facilities within the state. The Secretary would remain responsible for establishing quality standards for facilities and standards for accrediting bodies, and for oversight of state functions, and would retain authority to impose sanctions.

Accreditation

- o The Secretary may approve private nonprofit organizations or state agencies as accreditation bodies and must promulgate regulations under which the Secretary may approve an accreditation body not later than 9 months after enactment.
- o Requires the Secretary to establish standards for accreditation bodies including a requirement to review clinical images from accredited facilities at least every 3 years; prohibitions on financial relationships between reviewers and reviewed facilities; limits on accreditation fees; and a requirement for an annual survey of each facility by a medical physicist. The accrediting body must make annual onsite visits of a sample of facilities. The accrediting body must submit names of facilities on which action is taken and notify the Secretary of changes in standards.
- o The Secretary must promulgate regulations under which the Secretary may withdraw approval of an accrediting body.

- o The Secretary must annually evaluate the performance of each approved accreditation body, and report the results of the evaluation to the Senate Committee on Labor and Human Resources and the House Committee on Energy and Commerce.

Quality Standards

- o Requires the Secretary to establish standards for all mammography facilities, including standards with respect to:
 - + quality assurance and control to ensure reliability, clarity, and accuracy of mammograms and appropriate radiation dose,
 - + radiological equipment and equipment and materials used in conjunction with radiological equipment,
 - + qualifications of personnel performing mammography: 1) is licensed by a state to perform radiological procedures, or 2) is certified as qualified to perform radiological procedures by such an appropriate organization as the Secretary specifies in regulations and meets training standards, or, for a 2-year period, experience requirements,
 - + qualifications of physicians interpreting mammograms: 1) is certified as qualified to interpret radiological procedures by such an appropriate board as the Secretary specifies in regulations, or 2) is certified as qualified to interpret screening mammography procedures by such a program as the Secretary recognizes in regulation as assuring the qualifications of the individual with respect to such interpretation and meets training and experience requirements as established by the Secretary,
 - + qualifications of physicists surveying mammography facilities: 1) is licensed or approved by a state, 2) is certified in diagnostic radiological physics or certified as qualified to perform such surveys by a board specified by the Secretary in regulation, or 3) in the first five years after enactment, meets other comparable criteria established by the Secretary,
 - + maintenance of all mammograms in medical records and written reports of mammography results, with clarification that intent is not to limit patient access to records, and
 - + special techniques for mammography of patients with breast implants.

Inspections

- o Requires annual inspection of each certified mammography facility by the Secretary or by a state agency designated by the Secretary.
- o Requires the Secretary to annually inspect accredited facilities and certified facilities inspected by state agencies to assess the performance of the accreditation body or the state.

Sanctions

- o Authorizes the Secretary to impose upon a noncomplying facility a directed plan of correction and/or payment for the cost of onsite monitoring in lieu of suspension or revocation of certificate.
- o The Secretary may also impose civil money penalties, not to exceed \$10,000, for failure to obtain a certificate, for each day of failure to comply substantially with quality standards, permit inspection or make information available, or for each violation of this section by an owner, operator, or employee of a facility.

Suspension and Revocation

- o Authorizes the Secretary to suspend or revoke a facility's certificate if the owner, operator, or any employee is found guilty of misrepresentation in obtaining the certificate; has failed to comply with requirements or standards; has failed to comply with the Secretary's reasonable requests for records, information, reports, or pertinent records, or to inspect the facility; has violated or aided and abetted in the violation of any MQSA provision or implementing regulation; or has failed to comply with a sanction.
- o Suspension before a hearing is permitted where the violation charged presents a serious risk to human health and in certain other circumstances. An owner or operator of a facility whose certification is revoked is barred from owning or operating any such facility for 2 years.

Injunctions

- o The Secretary is permitted to bring suit seeking injunction against a facility operating without a certificate or engaging in activity constituting a serious risk to human health.

Judicial Review

- o Provides for direct appeal of sanctions to the Courts of Appeals with review by the Supreme Court.

Information

- o Requires the Secretary, by October 1, 1996, and annually thereafter, to compile and make available to physicians and the general public information useful in evaluating the performance of mammography facilities, including lists of facilities that have been the subject of specified adverse actions including convictions under Federal or state laws, sanctions, and certificate suspension or revocation.

State Laws

- o Specifically preserves states' authority to enact laws at least as stringent as this law or regulations under it.

National Advisory Committee

- o Requires the Secretary to establish a National Mammography Quality Assurance Advisory Committee to advise and assist in carrying out the law. The Committee's duties include determining, and reporting to the Congress by October 1, 1993, whether sufficient mammography facilities are available in rural and health professional shortage areas, and the effects of this section on such facilities, and the costs and benefits of compliance with this law.

Consultations

- o Requires the Secretary to consult with appropriate Federal agencies within the Department in carrying out the law.

Breast Cancer Screening Surveillance Research Grants

- o Requires the Secretary to award grants as she determines to be appropriate for the establishment of surveillance systems in selected geographic areas to provide data to evaluate the functioning and effectiveness of breast cancer screening programs in the U.S.

Funding

- o Requires the Secretary to assess fees from facility owners to cover the costs of inspections, and to have those fees deposited as an offset to the appropriations made to the Department.

- o Authorization of appropriation for the Secretary to carry out other activities which are not supported by fees, such sums as may be necessary for fiscal year 1993 through 1997.
- o Authorization of appropriation to award research grants, such sums as may be necessary for each of the fiscal years 1993 through 1997.

Study

- o Requires the Comptroller General to study the certification program authorized under the law to determine if the program has improved the quality and accessibility of mammography services, reduced the frequency of poor quality mammography, and improved the early detection of breast cancer, and to submit to the cognizant Committees an interim report by 3 years, and a final report by 5 years, after enactment.